

No. 22-11124

**United States Court of Appeals
for the
Eleventh Circuit**

LISA HILL LEONARD, AN INDIVIDUAL, AND LEONARD DRUGS INC. D/B/A THE DRUG
STORE, AN ALABAMA CORPORATION,
Plaintiffs-Appellants,

v.

THE ALABAMA STATE BOARD OF PHARMACY, A STATE LICENSING BOARD; BRENDA
DENSON, CHRIS PHUNG, ROBERT COLBURN, CHRISTY K. GARMON, AND GARY
MOUNT, IN THEIR OFFICIAL CAPACITIES AS MEMBERS OF THE ALABAMA STATE
BOARD OF PHARMACY AND INDIVIDUALLY,
Defendants-Appellees.

On Appeal from the
United States District Court
for the Middle District of Alabama, Eastern Division
Case No. 3:21-CV-596-ECM
(Honorable Emily C. Marks)

BRIEF OF APPELLANTS

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**CERTIFICATE OF INTERESTED PARTIES
AND CORPORATE DISCLOSURE STATEMENT**

Pursuant to Eleventh Circuit Rule 26.1-1, the undersigned counsel for plaintiffs-appellants certifies that, to the best of the undersigned counsel's knowledge, the following persons/entities have an interest in the outcome of this case:

1. Alabama Attorney General: counsel for Defendants-Appellees.
2. Alabama State Board of Pharmacy: Defendant-Appellee.
3. Colburn, Robert: Defendant-Appellee.
4. Davis, Richard E.: counsel for Plaintiffs-Appellants.
5. Denson, Brenda: Defendant-Appellee.
6. Doyle, Stephen M.: Magistrate Judge for the United States District Court for the Middle District of Alabama.
7. Garman, Christy: Defendant-Appellee.
8. Geer, III, John J.: former counsel for Plaintiffs.
9. Harrison, Alicia M.: counsel for Plaintiffs.
10. Hetzel, Tara: counsel for Defendants-Appellees.
11. Howell, Laura: counsel for Defendants-Appellees.
12. Kirkland, Catherine C.: former counsel for Plaintiffs.
13. Leonard, Craig: spouse of Plaintiff-Appellant Lisa Leonard and co-owner of Plaintiff-Appellant The Drug Store.
14. Leonard, Lisa Hill: Plaintiff-Appellant.
15. Leonard Drugs, Inc. d/b/a The Drug Store: Plaintiff-Appellant
16. Marks, Emily C.: Presiding Judge in the United States District Court for the Middle District of Alabama.

17. Mount, Gary: Defendant-Appellee.
18. Novak, III, Tabor R.: counsel for Plaintiffs.
19. Phung, Chris: Defendant-Appellee.
20. Starnes Davis Florie LLP: counsel for Plaintiffs-Appellants.
21. Ward, James: counsel for Defendants.
22. Ward & Cooper, LLC: counsel for Defendants.
23. Umbach, III, Arnold W.: counsel for Plaintiffs-Appellants.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, Appellant Leonard Drugs, Inc. d/b/a The Drug Store states that it has no parent company, and that there is no publicly held company which owns 10% or more of Leonard Drugs, Inc. d/b/a The Drug Store.

Dated: July 11, 2022.

This representation is made so the judges of this court may evaluate possible disqualification and recusal.

STATEMENT REGARDING ORAL ARGUMENT

While the appellants would welcome an opportunity to appear before the Court, they believe an expeditious disposition of this appeal can be reached without the need for oral argument.

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STATEMENT OF JURISDICTION

The District Court had jurisdiction under 28 U.S.C. §§ 1331, 1337(a), and 1343. This Court has appellate jurisdiction under 28 U.S.C. § 1291, with the appeal coming from a final decision of the District Court. Plaintiffs-Appellants filed a timely notice of appeal on April 5, 2022.

STATEMENT OF THE ISSUES¹

1. Whether the Public Readiness and Emergency Preparedness Act preempts the malpractice charges brought by the Alabama Board of Pharmacy against Lisa Leonard and The Drug Store, which all relate to the administration of COVID 19 antibody tests.

2. Whether the district court should have exercised its jurisdiction, and not abstained, to enjoin the Board's unlawful, and bad faith, prosecution that is facially and conclusively preempted by the PREP Act.

STATEMENT OF THE CASE ON APPEAL

I. Course of Proceedings and Disposition in the Court Below.

Plaintiffs filed this action on September 8, 2021. Doc. 1. Defendants filed a motion to dismiss and brief. Docs. 15 and 16. Plaintiffs filed an amended complaint on November 4, 2021, as well as an amended motion for preliminary injunction and order to maintain the status quo and brief. Docs. 32, 33, 34, 36, 38, 45.

On December 15, 2021, the district court held a hearing on defendants' motion to dismiss and plaintiffs' motion for preliminary injunction. Doc. 44. Following the hearing, and with the district court's permission, the parties filed affidavits. Docs.

¹ Plaintiffs are only appealing the specified issues and the associated dismissal of their claims for injunctive relief, which were dismissed without prejudice. Plaintiffs are not appealing the dismissal of the claims for damages against the Board members in their individual capacities, nor are they appealing the dismissal of the antitrust claim against the Board and its members in their official capacities.

52 and 54. The district court entered its memorandum opinion and order, Doc. 58, and final judgment, Doc. 59, granting defendants' motion to dismiss and denying plaintiffs' preliminary injunction on March 10, 2022. Plaintiffs timely filed their notice of appeal on April 5, 2022. Doc. 61.

II. Statement of the Facts

Lisa Leonard and her husband Craig have been licensed pharmacists in Alabama for over 30 years and own a pharmacy in Auburn, Alabama called The Drug Store. Doc. 45, p. 15. The Drug Store employs about eight employees. Doc. 45, pp. 15-16.

On January 31, 2020, Alex Azar, then-Secretary of the United States Department of Health and Human Services ("HHS"), declared a public health emergency for the entire United States "to aid in the nation's health care community response to the COVID-19 outbreak." Doc. 45, p. 17; Doc. 45-2, p. 2. On March 17, 2020, the Secretary issued a declaration under the PREP Act regarding the COVID-19 pandemic (the "Declaration") "to provide liability immunity for activities related to medical countermeasures against COVID-19," Doc. 45, pp. 19-20; Doc. 45-2, p. 2, specifically stating that he "determined that the spread of SARS-CoV-2 or a virus mutating therefrom and the resulting disease COVID-19 constitutes a public health emergency," Doc. 45-2, p. 5. The Declaration defines a "Covered Countermeasure" to include COVID-19 antibody testing. Doc. 45, pp. 19-20; Doc. 45-2, p. 6. The

Declaration was effective as of February 4, 2020. Doc. 45, pp. 19-20; Doc. 45-2, p. 2.

In early April 2020, after receiving emails from manufacturers of antibody tests, Lisa Leonard thought she could help her customers by offering the tests to determine if they had unknowingly been exposed to the virus and had developed antibodies. Doc. 45, p. 20.

On April 8, 2020, HHS issued a document titled “Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity Under the PREP Act” recognizing the need for “rapidly expanding COVID-19 testing across America.” Doc. 45-22, p. 2. On April 17, 2020 HHS’s Counsel released an opinion on the PREP Act affirming that serology tests constituted were covered under the Declaration and confirming “pharmacists are covered persons” and they are afforded the PREP Act’s “broad” immunity. Doc. 45, p. 22-23; Doc. 45-5, p. 7. On April 20, 2020, The Drug Store administered its first antibody test to customers. Doc. 45, p. 23.

In a May 19, 2020 opinion, the HHS Counsel concluded that the PREP Act, in conjunction with the Declaration, “preempts any state or local requirements that prohibits or effectively prohibits a pharmacist from ordering and administering a COVID-19 diagnostic test that the [FDA] has authorized.” Doc. 45, p. 25.

Around June 14, 2020, an investigator, Sean Malloy (“Malloy”), appeared at The Drug Store and told Lisa Leonard that the Board had received a complaint

regarding *privacy practices* at The Drug Store. Doc. 45, p. 26. No citation was issued; no mention was made to Lisa Leonard of any problems with COVID-19 antibody testing. Doc. 45, p. 26.

In late July 2020, Board investigator Glenn Wells (“Wells”) called Lisa Leonard regarding an antibody testing complaint from Chuck Beams (“Beams”), a competing pharmacist. Doc. 45, p. 33.² Wells’ July 2020 telephone call was not his first encounter with Lisa Leonard. Doc. 45, p. 33-34. In 2005, Wells visited The Drug Store, and Leonard and Wells had an interaction not witnessed by anyone: Leonard said that Wells pulled a gun on her; Wells denied doing so. Doc. 45, p. 33-34. In any event, Leonard regarded the matter as fully resolved. Doc. 45, p. 33-34.

On August 6, 2020, Ariel Gainey (“Gainey”), an off-duty Prattville police officer, went to The Drug Store in Auburn, requested to be tested for COVID-19 antibodies, and was tested. Doc. 45, p. 31. Gainey secretly recorded a video of the encounter for the Board, but the video establishes no wrongdoing. On August 7, 2020, in response to Beams’ request for an update, Malloy states, “*If all goes the way we plan*, then I believe we will stop any further issues from The Drug Store.” Doc. 45, pp. 31-32; Doc. 45-19 (emphasis added).

² As of July 28, 2020, plaintiffs had administered approximately 4400, or 74%, of the antibody tests without a single customer complaint or confusion about test results being expressed to them. Doc. 45, p. 33.

On August 26, 2020, Malloy and Wells appeared at The Drug Store, and Wells asserted that the tests administered by The Drug Store were inaccurate. Doc. 45, pp. 34-35. Neither told Leonard to stop giving the tests and did not issue any citation. Doc. 45, pp. 34-35.³ In September 2020, The Drug Store stopped administering antibody tests without having been directed or ordered to do so by the Board. Doc. 45, p. 35.

On September 23, 2020, Board Investigator Mark Delk (“Delk”) visited The Drug Store and asked Lisa and Craig Leonard to provide handwritten statements regarding the long-resolved 2005 incident involving Wells pulling his gun without allowing the Leonards to have a copy of their statements. Doc. 45, p. 37.

In October 2020, HHS released guidance stating that the Declaration specifically applied to pharmacy technicians and identified pharmacy technicians as “covered persons,” that pharmacy technicians may administer “COVID-19 tests, including serology tests,” and that HHS’ guidance on pharmacy technicians specifically “preempts any state and local law that prohibits or effectively prohibits those who satisfy these requirements from administering COVID-19 tests.” Doc. 45, p. 36; Doc. 45-22, p. 5. HHS further issued a December 9, 2020 amendment to the

³ As of August 26, 2020 approximately 5,580, or 93.8% of the antibody tests administered by plaintiffs had been performed without any customer complaint or confusion about results having been communicated to plaintiffs, nor any citation or cease-and-desist or other order having been issued by the Board. Doc. 45, pp. 34-35.

Declaration, stating that “pharmacists, pharmacy interns, and pharmacy technicians who order or administer certain COVID-19 tests and certain vaccines” are both covered persons and qualified persons under the PREP Act, *retroactive to February 4, 2020*. Doc. 45, pp. 36-37; Doc. 45-23, p. 2. HHS also issued a January 19, 2021 opinion to reinforce that the PREP Act provides complete preemption to “state and local requirements that would prohibit or effectively prohibit qualifying state-licensed pharmacists covered by a declaration from ordering and administering FDA-approved COVID-19 tests[.]” Doc. 45, pp. 37-38; Doc. 45-24, p. 4.

On March 9, 2021, the Board issued a Statement of Charges against Lisa Leonard and The Drug Store all relating to the administration of COVID-19 antibody tests in some manner. Doc. 45, pp. 38-39; Doc. 45-25. The Board subsequently amended its charges, Doc. 45, p. 40; Doc. 45-28.⁴ On January 11, 2022, the Board moved to again amend the charges, still consisting entirely of claims regarding the administration of COVID-19 antibody tests, and the motion remains pending, Doc. 55-2.

A total of 5,949 tests were administered at The Drug Store without a single incident or complaint of physical injury, infection, or other adverse customer outcome. Doc. 45, p. 42.

⁴ Lisa Leonard and The Drug Store filed answers denying all charges. Doc. 45, pp. 39-40; Doc. 45-26; Doc. 45-27; Doc. 45-29; and Doc. 45-30.

III. Standard of Review

In this Circuit, a district court’s decision whether to abstain from exercising jurisdiction under *Younger v. Harris*, 401 U.S. 37, 45 (1971) is reviewed for abuse of discretion. *31 Foster Children v. Bush*, 329 F.3d 1255, 1274 (11th Cir. 2003); *Boyer v. Shell Oil Prods. Co.*, 199 F.3d 1260, 1265 (11th Cir. 2000); but see *Phelps v. Hamilton*, 122 F.3d 885, 889 (10th Cir. 1997)(applying de novo review to *Younger* abstention decisions). “‘There is little practical distinction between review for abuse of discretion and review de novo’ in abstention cases, inasmuch as the district court’s discretion to abstain ‘is narrowed by a federal court’s obligation to exercise its jurisdiction in all but the most extraordinary cases.’” *United States v. Commonwealth of Kentucky*, 252 F.3d 816, 825 (6th Cir. 2001)(quoting *Hachamovitch v. DeBuono*, 159 F.3d 687, 693 (2d Cir. 1998)).

SUMMARY OF THE ARGUMENT

Through the PREP Act, Congress promised healthcare providers who joined the fight against COVID-19 that they would not have to worry about liability or even being sued for the measures they took for the good of our country. Lisa Leonard and her pharmacy responded to the call by offering antibody tests to their customers. She is now being prosecuted by the Alabama Board of Pharmacy, at the apparent urging of one of her competitors, for doing what Congress asked her to do. The Board has brought regulatory “malpractice” charges against her and her pharmacy, threatening

to strip her of her license and impose a six-figure fine. The Board says it is not disciplining her for giving antibody tests; rather, its charges relate to the “manner” in which the COVID-19 antibody tests were administered.

The immunity Congress granted in the PREP act is immunity from “suit and liability.” That immunity extends to any action by a pharmacy, pharmacist, or pharmacy technician related to the administration of COVID testing. The PREP Act also expressly preempts any conflicting state law and preempts any action by a state licensing body that conflicts with the terms of the Act.

Leonard and her pharmacy could not be sued by a customer for malpractice relating to a COVID-19 antibody test (and none have complained). Yet the Board is charging Leonard and her pharmacy with malpractice for *how* they allegedly administered COVID-19 antibody tests. This state agency prosecution is therefore in conflict with the immunity protections Congress extended to healthcare providers like Leonard and The Drug Store and is therefore preempted.

The Board struggles to explain how its actions are consistent with federal law. Its primary defense in federal court is to say it should be allowed to decide whether its own actions are consistent with federal law. That is, it urges abstention. However, abstention will result in irreparable harm (and already has) and will force Leonard and her pharmacy to undergo prosecution when Congress guaranteed them immunity from suit. The district court was therefore wrong to abstain. If this Court does not

reverse that decision, Leonard and her pharmacy will lose the protection Congress granted them, will be driven out of business, and other healthcare providers will be discouraged from joining the fight in the next health care crisis.

ARGUMENT

I. The Board’s Charges Are Preempted by the PREP Act.

A. The PREP Act was created by Congress for emergencies.

Congress created the PREP Act to encourage healthcare providers to participate in the response to national emergencies. Congress delegated authority to HHS to implement the Act. On January 31, 2020, the HHS Secretary declared a public health emergency “to aid in the nation’s health care community response to the COVID-19 outbreak.” Doc. 45-2, p. 2. On March 17, 2020, the Secretary issued a declaration, retroactive to February 4, 2020, that provided liability immunity to healthcare providers—including retail pharmacies, pharmacists, and pharmacy technicians—covering, among numerous other activities, the administration of COVID-19 tests. Doc. 45-2, pp. 2-7.

B. The PREP Act confers protection from “suit and liability.”

The PREP Act states,

(1) In general

Subject to the other provisions of this section, a covered person *shall be immune from **suit and liability** under Federal and State law* with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered

countermeasure if a declaration under subsection (b) has been issued with respect to such countermeasure.

(2) Scope of claims for loss

(A) Loss

For purposes of this section, the term “loss” means *any type of loss*, including—

(i) death;

(ii) physical, mental, or emotional injury, illness, disability, or condition;

(iii) fear of physical, mental, or emotional injury, illness, disability or condition, including any need for medical monitoring; and

(iv) loss of or damage to property, including business interruption loss.

Each of clauses (i) through (iv) applies without regard to the date of the occurrence, presentation, or discovery of the loss described in the clause.

(B) Scope

The immunity under paragraph (1) applies to *any claim* for loss *that has a causal relationship with the administration to or use by an individual of a covered countermeasure*, including a causal relationship with the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure.

42 U.S.C. § 247d-6d(a)(1) and (2)(A) and (B)(emphasis added).

On its face, the PREP Act provides immunity from suit *and* liability. Given this immunity, a pharmacy cannot be sued or be liable for providing COVID-19

tests, and a pharmacist cannot be sued or liable for giving an antibody test. The immunity precludes *both* suit and liability for *any* outcome of the administration of a test—adverse patient reactions, test misinterpretation, or anything else—unless each plaintiff proves, by clear and convincing evidence, willful misconduct that proximately caused serious physical injury or death. 42 U.S.C. § 247d-6d(c)(3). The scope of immunity also includes circumstances in which a COVID-19 test was administered by a pharmacist or pharmacy in circumstances in which the “covered person” reasonably could have believed “that the [test] was administered to or used in accordance with the conditions [of a declaration].” 42 U.S.C. § 247d-6d(a)(4)(B).

C. The PREP Act expressly preempts requirements that are “different from” or “in conflict with” the requirements of the PREP Act.

The PREP Act also contains an express preemption provision that provides, in pertinent part, as follows:

(8) Preemption of State law

During the effective period of a declaration under subsection (b), or at any time with respect to conduct undertaken in accordance with such declaration, *no State or political subdivision of a State may establish, enforce, or continue in effect* with respect to a covered countermeasure *any provision of law or legal requirement* that—

(A) *is different from, or is in conflict with, any requirement* applicable under this section; and

(B) *relates to the...sale, donation, purchase, marketing, promotion, packaging, labeling, licensing, use, any other aspect of safety or efficacy, or the prescribing, dispensing,*

or administration by qualified persons of the covered countermeasure, or to any matter included in a requirement applicable to the covered countermeasure under this section or any other provision of this chapter, or under the Federal Food, Drug, and Cosmetic Act.

42 U.S.C. § 247d-6d(b)(8)(emphasis added). This express preemption provision cannot be more clear, comprehensive, and facially conclusive in its effect whether read by itself, in conjunction with subsection (a)(1)’s immunity, or in the context of the PREP Act as a whole. The PREP Act is an emergency statute for emergent times, so Congress has made absolutely clear that the Secretary’s actions are not to be the subject of interference. The HHS Counsel’s January 19, 2021 opinion squarely addressed express preemption by the Act well before the Board filed its charges on March 9, 2021: “*We conclude that the Act expressly preempts state and local requirements to the extent that they would effectively prohibit qualifying pharmacists from ordering and administering COVID-19 tests and vaccines authorized by the Secretary’s declaration.*” Doc. 45-24, p. 4; emphasis added.

D. All of the Board’s charges “relate to” the administration of COVID-19 antibody testing.

On the face of the latest iteration of the Board charges, as in the prior versions, there can be no question that the defendants’ target is plaintiffs’ administration of COVID-19 tests as these examples conclusively show:

Count One

Violating Code of Alabama (1975), § 34-23-33(6) prior to and/or on or about September 9, 2020 by *administering*

COVID-19 Antibody Test(s) (Test) which you represented would provide a diagnosis for COVID-19....

Doc. 55-2, p. 3 (emphasis added).

Count Eight

Violating Code of Alabama (1975), § 34-23-33(6) prior to and/or on or about September 9, 2020 ***by administering COVID-19 Antibody Test(s)***....

Doc. 55-2, p. 5 (emphasis added).

Count Fifteen

Violating Code of Alabama (1975), § 34-23-33(6) prior to and/or on or about September 9, 2020 based upon the following:

a. Allowing JoAnna Taylor, a Pharmacy Technician, to represent that the ***Test would provide a diagnosis for COVID 19***....

Doc. 55-2, p. 7 (emphasis added).

Count Sixteen

Violating Code of Alabama (1975), § 34-23-33(6) prior to and/or on or about September 9, 2020 by ***not having or utilizing a Sharp container for lancets used in the administration of the COVID-19 Antibody Test***.

Doc. 55-2, p. 7 (emphasis added).

Count Twenty-Three

Violating Code of Alabama (1975), § 34-23-33(6) prior to and/or on or about September 9, 2020 in a number of times unknown to the Board by ***allowing the use of the same alcohol swab to clean the patient's finger prior to the administration of the COVID-19 Antibody Test*** (Test) and reusing the same swab to wipe off any blood resulting

from the above referenced Test, to include allowing Taylor to engage in the above described conduct.

Doc. 55-2, p. 9 (emphasis added). All other counts are also, without exception, predicated on plaintiffs' "administering COVID-19 Antibody Tests." Doc. 55-2, pp. 3-14.

Defendants have expressly acknowledged that *all* charges are for "administering COVID-19 Antibody Tests," Doc. 16., p. 16 (emphasis added), and that the charges "challenge the *manner* in which Plaintiffs administered the COVID-19 antibody tests," Doc. 16., p. 20 (emphasis in original). Defendants have also acknowledged that "[the charges] are aimed at preventing them [Lisa Leonard or The Drug Store] from performing them [the COVID antibody tests] incorrectly in a manner that constitutes malpractice under the board's own rules and regulations." Tr. at 34:19-22.

E. The Board's charges are requirements "different from" and "in conflict with" the PREP Act's requirement of immunity for COVID-19 testing, and the charges are expressly preempted as a result.

Congress made clear, by the express preemption provision, that no state or political subdivision of a state can "establish, *enforce*, or continue in effect" *any* provision of law or legal requirement that prohibits or effectively prohibits licensed pharmacists from ordering and administering COVID-19 tests or retail pharmacies from distributing the tests. 42 U.S.C. § 247d-6d(b)(8). All of the Board's charges

against Leonard and The Drug Store are preempted because the charges seek to impose regulatory licensing sanctions for liability for “malpractice,” but they cannot because of the immunity and preemption provisions: “Pharmacists, who would be immune under the Secretary’s declaration, could hardly order and administer COVID-19 tests or vaccines *if the States could impose penalties for the same activity by revoking their licenses*. Such state or local requirements would threaten to make the Secretary’s authorizing identification a practical nullity.” Doc. 45-24, p. 11 (emphasis added).

If the Board is allowed to enforce “any provision of law or legal requirement” to stop a pharmacist from administering COVID-19 tests, then the PREP Act and the Declaration are rendered a nullity. Doc. 45-24, p. 11.⁵ In *Parker v. St. Lawrence County Pub. Health Dept.*, the court was not persuaded by the plaintiff’s argument, similar to the defendants’ argument here, that it was the administration of the vaccine without consent—that is, the “manner” of administration, not the vaccination *per se*—that was the problem. See 102 A.D. 3d 140, 144 (N.Y.S. 2012)(“we must presume that Congress fully understood that errors in administering a vaccination program may have physical as well as emotional consequences, and determined that

⁵ See *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 447 (2005)(state requirements that are not “equivalent to, and fully consistent with” federal requirements differ from them and are preempted).

such potential tort liability must give way to the need to promptly and efficiently respond to a pandemic or other public health emergency”).

The immunity that is triggered by a declaration is the most fundamental requirement of the PREP Act, and, as a requirement, immunity is expressly dovetailed with the Act’s express preemption provision. *See* 42 U.S.C. § 247d-6d(a)(1), (b)(8). The Act preempts state and local requirements that prohibit or effectively prohibit state-licensed pharmacists from administering COVID-19 antibody tests, including diagnostic tests, because such prohibitions “relate to” the administration of tests and “differ from” and “conflict with” the authorization provided by HHS. Doc. 45-24, p. 4 and n.5, pp. 6-7. The PREP Act also *requires* that immunity from “suit or liability” is provided for the administration of such tests, 42 U.S. C. § 247d-6d(a)(2)(B). Without question, then, “Congress specified that state or local health officials lack authority to take measures that would conflict with” the HHS effort “to act quickly to expand the number of covered persons” who may administer tests “[i]n view of the magnitude of the COVID-19 pandemic here.” Doc. 45-24, p. 15.

The defendants say they are not charging plaintiffs with administering the tests, but for the manner in which they administered them and for “performing them incorrectly in a manner that constitutes malpractice.” Doc. 16, p. 20; Tr. at 34:20-21. But the PREP Act itself and the Declaration clearly cover the administration of

a test, the manner in which a test is administered, and how the test is performed. Congress expressly drew the line between what a state could regulate and what it cannot, and Congress intentionally drew both the immunity and the preemption very broadly to support the emergency purposes of the statute. There is nothing more that a court needs to do beyond reading the expansive language of the statute and applying it to the charges levied by the Board. The Board's charges conflict with the immunity requirement of the Act, and the charges are therefore expressly preempted and without legal effect because the charges have effectively prohibited or have prohibited the administration of COVID-19 antibody tests by Lisa Leonard and The Drug Store.

II. The District Court Was Wrong to Abstain and Should Have Enjoined the Board from Proceeding with Its PREP Act-Preempted Charges.

In ruling on the parties' motions, the district court declined to exercise its jurisdiction over plaintiffs' preemption claim, dismissing it without prejudice based on the abstention doctrine announced by the Supreme Court in *Younger v. Harris*, 401 U.S. 37, 45 (1971). As demonstrated below, that decision was an abuse of discretion and should be reversed.

This Court has recognized, “[t]he Supreme Court has said that federal courts have a ‘virtually unflagging obligation...to exercise the jurisdiction given them.’” *31 Foster Children v. Bush* 329 F.3d 1255, 1274 (11th Cir. 2003)(quoting *Col. River Water Conservation Dist. V. United States*, 424 U.S. 800, 817 (1976)). “But

‘virtually’ is not ‘absolutely,’ and in exceptional cases federal courts may and should withhold equitable relief to avoid interference with state proceedings.” *Id.* at 1274 (quoting *New Orleans Pub. Serv., Inc. v. Council of New Orleans*, 491 U.S. 350, 359 (1989)). “While non-abstention remains the rule, the *Younger* exception is an important one. It derives from ‘the vital consideration of comity between the state and national governments.’” *Id.* (quoting *Luckey v. Miller*, 976 F.2d 673, 676 (11th Cir. 1992)).

In *Younger*, the Court held that “absent extraordinary circumstances federal courts should not enjoin pending state criminal prosecutions.” *New Orleans Pub. Serv., Inc. v. Council of City of New Orleans*, 491 U.S. 350, 364 (1989)(hereinafter “*NOPSP*”). *Younger* has been extended to apply to state civil and administrative proceedings. *See, e.g., Huffman v. Pursue, Ltd.*, 420 U.S. 592 (1975). *Younger* requires federal courts to abstain where (1) there is an ongoing state judicial proceeding, (2) the proceeding implicates important state interests, and (3) there is an adequate opportunity in the state proceeding to raise constitutional challenges. *Middlesex County Ethics Comm. v. Garden State Bar Ass’n*, 457 U.S. 423, 432 (1982). When the *Middlesex* factors are satisfied, a court should abstain unless there are “extraordinary circumstances.” *Kugler v. Helfant*, 421 U.S. 117, 124 (1975). *Younger* explained that extraordinary circumstances exist where there is “bad faith” or “harassment” by state officials responsible for the prosecution, where the state

law being applied is “flagrantly and patently violative of express constitutional prohibitions,” or where there are “extraordinary circumstances in which the necessary irreparable injury can be shown even in the absence of the usual prerequisites of bad faith and harassment.” *Younger*, 401 U.S. at 53-54; *Kugler*, 421 U.S. at 124.

A. Plaintiffs do not have an adequate opportunity before the Alabama Board of Pharmacy to raise the *immunity from suit* granted them by the PREP Act or the preemption of the Board’s charges.

The district court determined that all three of the *Middlesex* factors are met in this case. By failing to consider the PREP Act’s grant of immunity *from suit*, as opposed to just liability, the court below incorrectly analyzed the third factor—whether plaintiffs have an adequate opportunity to raise preemption by the PREP Act in the proceedings before the Board.

The immunity central to Congress’ purpose in enacting the PREP Act is immunity from “suit and liability.” Courts should interpret statutes in a way that avoids redundancy. *Corley v. United States*, 556 U.S. 303, 314 (2009). To achieve this goal, courts must construe statutes in a way that gives effect to every word if possible. *Loughrin v. United States*, 573 U.S. 351, 358 (2014). Furthermore, courts should adopt the plain and ordinary meaning of a statute’s words. *Bostock v. Clayton Cnty., Ga.*, 140 S. Ct. 1731, 1743 (2020). Courts must also interpret statutes in a way that honors the purpose of the statute. *Gundy v. United States*, 139 S. Ct. 2116, 2126

(2019). These fundamental rules of statutory construction require that the word “suit” be given meaning. By using this word, Congress intended to protect covered persons not only from being legally responsible, but also from having to answer for their actions. Congress included the word “suit” to protect healthcare providers, like Leonard, from having to defend themselves against legal action based on steps taken to fight public health threats. If Congress only intended to give providers a defense to liability, it would not have said “suit *and* liability.”

In the district court, the Board argued, that plaintiffs have an adequate opportunity to raise their preemption claim under the Supremacy Clause before the Board and in a subsequent appeal to an Alabama state court. However, this argument ignores the PREP Act’s grant of immunity from “suit and liability.” If the Act only said “liability,” the Board’s argument might make sense. However, because it is facially obvious from the Act that Congress also intended to protect covered persons from “suit,” plaintiffs *must* have an opportunity to invoke the Act’s protections *before* their right to be immune from suit is taken. Otherwise, it is too late. Leonard and The Drug Store will have suffered irreparable harm. Once they are prosecuted by the Board, immunity from “suit” cannot be restored.

The Supreme Court’s qualified immunity jurisprudence is analogous, and the concerns behind the qualified immunity doctrine are broader than protecting public officials from monetary damages. The concerns also include “the general costs of

subjecting officials to the risks of trial – distraction of officials from their governmental duties, inhibition of discretionary action, and deterrence of able people from public service.” *Harlow v. Fitzgerald*, 457 U.S. 800, 816 (1982). Because of these concerns, the Court held that decisions denying qualified immunity are immediately appealable before a final judgment: “[t]he entitlement is an *immunity from suit* rather than a mere defense to liability; and like an absolute immunity, it is effectively lost if a case is erroneously permitted to go to trial.” *Mitchell v. Forsyth*, 472 U.S. 511, 526 (1985).

Similar concerns underlie the PREP Act. Congress sought to enlist and encourage healthcare providers to take steps, in the public interest, to fight infectious diseases creating emergencies like the COVID-19 pandemic. The promise Congress made was not just liability protection but also freedom from defending actions—immunity *from suit*. Without the opportunity to raise—and have decided—a claim of PREP Act immunity before having to defend oneself before a state licensing board, Congress’ promise of immunity from suit is empty.

The Eleventh Circuit does not appear to have specifically addressed whether the opportunity to raise a federal constitutional challenge in a state forum must come before having to defend oneself in the state proceeding to be adequate under the third prong in *Middlesex*. Decisions in the Ninth Circuit have recognized that there must be an opportunity to have the federal claim addressed before a deprivation occurs or

administrative discipline is imposed. *See Baffert v. California Horse Racing Board*, 332 F.3d 613, 620 (9th Cir. 2003)(“there are instances in which timeliness plays a role in the adequacy of the state forum” but ultimately concluding the plaintiff was able to have federal claims adjudicated before serving a suspension); *Kenneally v. Lungren*, 967 F.2d 329, 333 (9th Cir. 1992)(plaintiff had an opportunity to have federal claims addressed before the Board’s license revocation took effect).

In *Adibi v. Cal. State Bd. of Pharmacy*, 393 F. Supp. 2d 999, 1010-11 (N.D. Cal. 2005), in which a pharmacist obtained an injunction of a pharmacy board’s effort to revoke his license, the court discussed the third *Middlesex* factor, and explained that, to have an adequate opportunity to raise a federal claim in a state proceeding, the plaintiff must have the ability to raise the claim **and have it decided** in a timely fashion. To be timely, it must be pre-deprivation. In other words, there must be an opportunity to have the federal claim addressed on the merits before an adverse administrative action. In *Adibi*, state law did not allow the plaintiff to have his constitutional challenge to the pharmacy board’s charges decided *before* his license was revoked, so the district court decided that *Younger* abstention was not appropriate and denied the pharmacy board’s motion to dismiss.

Here, because of the PREP Act’s grant of immunity from suit, it is not enough that Alabama law allows Leonard and The Drug Store to “raise” preemption before revocation of their licenses. By that time, it is too late. Plaintiffs will have lost their

right to have immunity from suit decided under federal law. There is no opportunity under Alabama law or the Board's procedures for plaintiffs to have their right to immunity from suit adjudicated before being prosecuted. According to the Board's procedures, the Board members do not convene until the time of the hearing. They are not supposed to be made aware of the charges until the time of the hearing, and they are not supposed to deliberate until after all evidence is presented at the hearing. Doc. 52-1, Yeatman affidavit ¶¶ 10, 17. Plaintiffs' only opportunity for either preemption or immunity to be addressed the PREP Act intends is in federal court.

B. Plaintiffs' immunity from suit and liability preempting the Board's charges is "facially conclusive."

The Supreme Court has expounded on the exception for irreparable injury more fully since *Younger*. In *Kugler v. Helfant*, 421 U.S. 117, 123-25 (1975), as it relates to a claim of federal preemption under the Supremacy Clause, the Court explained that irreparable harm that would constitute an exception to *Younger* may exist where the state proceeding is "flagrantly and patently violative of express constitutional prohibitions...." In *NOPSI*, the Court announced that a "facially conclusive" claim of preemption would meet the irreparable injury exception. 491 U.S. at 367.⁶

⁶ The plaintiff in *NOPSI* did not meet the standard because "the state's acts were not directly or even indirectly foreclosed by the federal statute, the regulations implementing it, or the case law applying it." *Id.* Here the Board's acts are directly preempted and therefore "foreclosed."

This Court has applied the “facially conclusive” standard since *NOPSI*. In *Hughes v. Att’y Gen. of Fla.*, 377 F.3d 1259 (11th Cir. 2004), airline pilots sought to enjoin the State of Florida’s criminal prosecution of them for operating an aircraft while under the influence of alcohol on the grounds that the prosecution was preempted by regulations of the Federal Aviation Administration. The Eleventh Circuit reversed the district court’s decision not to abstain after concluding that the pilots’ preemption claim was not “facially conclusive.” *Id.* at 1265. “[O]nly the clearest of federal preemption claims would require a federal court to hear a preemption claim when there are underlying state court proceedings and when that claim can be raised in the state forum.” *Id.*; but see *Baggett v. Dept. of Prof’l Reg.*, 717 F.2d 521, 524 (11th Cir. 1983)(reversing a district court’s decision to abstain, because federal preemption was “readily apparent,” the standard applied in this Circuit before *NOPSI*). While we have found no other cases in this circuit that add contour to the “facially conclusive” standard, the Sixth Circuit has added helpful definition to the standard. In *United States v. Commonwealth of Kentucky*, 252 F.3d 816 (6th Cir. 2001), the appellate court determined, for purposes of *Burford* abstention, that the plaintiff had presented a “facially conclusive” preemption claim because the court “was not required to make a detailed analysis of state law, make factual findings, or inquire beyond the challenged statute’s four corners in finding that the state act was pre-empted.” *Marathon Petroleum Co. LLC v. Stumbo*, 528 F.

Supp.2d 639, 650 (E.D. Ky. 2007)(applying this definition in the context of *Younger* abstention).

The Board's prosecution of charges against Leonard and her pharmacy are clearly preempted by the PREP Act. All of the charges levied against them are, on their face, directly related to antibody testing. Even the gun charge is related to the Board's "investigation" of antibody testing by Lisa Leonard and her pharmacy. It is not necessary for this Court to go beyond the four corners of the Board's charges, analyze state law, or make any factual findings.

C. Plaintiffs have alleged more than sufficient specific facts to support federal jurisdiction based on the "bad faith" exception to *Younger*.

The third exception to *Younger* abstention applies if a state proceeding is brought in bad faith or for harassment. *Younger*, 401 U.S. at 53-54. "The policy of equitable restraint expressed in *Younger v. Harris*, in short, is founded on the premise that ordinarily a pending state prosecution provides the accused a fair and sufficient opportunity for vindication of federal constitutional rights." *Kugler*, 421 U.S. at 124. Put more simply, a proceeding is brought in bad faith when there is no expectation of obtaining a valid conviction. *Redner v. Citrus Cty.*, 919 F.2d 646, 650 (11th Cir. 1990). Bad faith also includes impermissibly motivated prosecutions brought to harass the target of the state proceeding. *See, e.g., Cameron v. Johnson*, 390 U.S. 611, 619 (1968); *Fitzgerald v. Peek*, 636 F.2d 943, 945 (5th Cir. 1981); *Wilson v. Thompson*, 593 F.2d 1375, 1387 (5th Cir. 1979).

In their Complaint, plaintiffs allege the following facts. Board investigator Malloy first visited Leonard at The Drug Store about an alleged patient complaint regarding privacy practices. According to the Board's website at the time, Lee County, Alabama, where The Drug Store is located, is not in Malloy's territory. Malloy made no mention of antibody testing and issued no citation. Doc. 45, p. 26. Thereafter, Beams, a competing pharmacist at the East Alabama Medical Center ("EAMC"), called The Drug Store pretending to be a customer wanting a COVID antibody test. Doc. 45, p. 28. He called back several other times and asked questions about antibody testing without identifying himself. Doc. 45, p. 29. He later called and identified himself as a pharmacist at EAMC, he said the antibody tests being given by The Drug Store were contradicting the tests given at EAMC, and he told Leonard to stop testing and that *Leonard had not heard "the end of this."* Doc. 45, p. 29 (emphasis added). Beams complained about The Drug Store by email to several state officials/agencies, including the Board. Doc. 45, p. 30. Malloy responded to Beams by saying "Fantastic thank you sir!" Doc. 45, p. 31. An off-duty police officer next appeared at The Drug Store asking to be given an antibody test, she attempted to video-record the encounter, and provided the garbled video to the Board. Doc. 45, p. 31. In response to Beam's request for an update, Malloy said in an email, "*If all goes the way we plan*, then I believe we will stop any further issues from The Drug Store." Doc. 45, pp. 31-32 (emphasis added). Then Wells became involved. Lee

County was not his assigned territory, either. Doc. 45, p. 33. He and Leonard had a contentious and highly disputed encounter in 2005, in which Leonard maintained that Wells pulled a gun on her, but Wells denied it. Doc. 45, pp. 33-34. Another investigator, Delk, visited The Drug Store in 2020 and demanded written statements regarding the 2005 gun incident between Leonard and Wells. Doc. 45, p. 37.

The district court cited *Phelps v. Hamilton*, 122 F.3d 885, 889 (10th Cir. 1997) for the proposition that plaintiffs must present more than “mere allegations of bad faith or harassment.”⁷ At the pleading stage, however, plaintiffs *must* rely on their allegations. There has been no opportunity for discovery. But, here, plaintiffs have, indeed, offered more than allegations. Their complaint attaches many documents, including incriminating email correspondence to and from Board investigators. The parties also submitted affidavits after the hearing with the district court’s permission. The Board has not contested the allegations of facts in the complaint with other facts, so the facts must be construed in plaintiffs’ favor on a Rule 12(b) motion. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

The district court said, “Assuming without deciding that the Plaintiffs have sufficiently alleged that Mr. Beams, Mr. Malloy, Mr. Delk, and Mr. Wells were

⁷ In *Phelps*, the district held an evidentiary hearing to allow the parties to present evidence of bad faith. *Id* at 890 n. 4.

biased or had an anticompetitive motive (or both), the Plaintiffs have not alleged facts from which the Court could reasonably infer that the Board adopted such bias or anticompetitive motive -- or that the Board was even aware of it.” Doc. 58, p. 29. The district court simply accepted the Board’s argument that it cannot be held responsible for the bad faith actions of the investigators it employs. Putting that issue aside, what this argument misses is that Leonard and The Drug Store have a right to be free from a prosecution motivated to harass and brought in bad faith. Stated another way, “[w]hen the federal right sought to be protected is the right not to be subjected to a bad faith prosecution or a prosecution brought for the purposes of harassment, the right cannot be vindicated by undergoing the prosecution.” *Shaw v. Garrison*, 467 F.2d 113, 122 n. 11 (5th Cir. 1972). The process of bringing charges against a pharmacist or a pharmacy is initiated by investigators. It is no answer to say a Board of impartial members will be the ultimate arbiter. *See Pettway v. Marshall*, 2019 WL 3752475, at *1 (N.D. Ala. Aug. 8, 2019)(rejecting similar argument that the Attorney General’s bad faith seizure of a bank account is cured by the fact that the forfeiture procedure is ultimately decided by an impartial judge).

Finally, the district court dismissed plaintiffs’ argument that the illegality of the Board’s prosecution demonstrates bad faith. Doc. 58, p. 31. The court below reasoned that if illegality of state action under federal law was sufficient to show bad faith, then the bad faith exception would swallow the *Younger* rule of abstention

from interference with state court proceedings. *Id.* This reasoning is flawed for two reasons. It overlooks that the bad faith standard can be met by showing that a prosecution is undertaken without hope of a valid conviction. Surely, whether the prosecution is facially illegal is relevant in the analysis. As demonstrated above, the Board's charges against Leonard and The Drug store for administration of COVID antibody testing is clearly preempted by the PREP Act. The Board, like all citizens, is presumed to know the law, especially the law that specifically applies to its area of expertise. Before the Board issued charges against the plaintiffs, HHS had made clear in many publications that the PREP Act applies to pharmacies and their employees, covered antibody testing, and that state licensing measures that burden the administration of COVID testing are preempted. Second, the "facially conclusive" preemption by the PREP Act makes this case different than just any case where illegality under federal law is alleged.

Plaintiffs have alleged plentiful facts to show that they have been subjected to investigation and prosecution for facially preempted charges of pharmacy "malpractice" initiated and maintained in bad faith and that coerced them to stop antibody testing, which the PREP Act encouraged them to do to help fight the pandemic, and for the purpose of harassment to ultimately drive them out of business. The defendants illegally succeeded in getting the plaintiffs to stop testing.

This Court should halt the Board's effort to put Leonard and The Drug Store out of business.

CONCLUSION

Plaintiffs face an absolute existential threat—including loss of license and financial penalties. The Court of Appeals (1) should find that the Board's charges and other measures are in conflict with the PREP Act's immunity requirement and, therefore, that the Act preempts the Board's charges and renders them of no legal effect; (2) find that the district court erred in abstaining from enjoining the defendants from prosecuting the charges and other adverse actions against Lisa Leonard and her pharmacy; and (3) should reverse and render with instructions for the district court to enter judgment in Lisa Leonard's and her pharmacy's favor, including a permanent injunction against further prosecution on the charges alleged.

Respectfully submitted on July 11, 2022,

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1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B)(i) because this brief contains 7,161 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f), as counted by the word count function of Microsoft Word word processing software.

2. This brief complies with the typeface requirement of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionately spaced typeface using the Microsoft Word word-processing software in 14-point Times New Roman font.

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The foregoing Brief of Appellants has been filed with the Clerk of the Court for the U.S. Court of Appeals for the Eleventh Circuit using the CM/ECF system, which is supposed to send a copy to the following:

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